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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hildebrand et al.) Atty Dkt No: 66802.055
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Serial No: 10/669,925) Examiner: M. DiBrino
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Filed: September 24, 2003) Art Unit: 1644
)
Customer No.: 30589) Confirmation No.: 4622

For: ANTI-HLA ASSAY AND METHODS

MAIL STOP - AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

I, William H. Hildebrand, hereby declare that I am a co-inventor of the invention claimed in the subject application, and I am a co-author of the Prilliman et al. (*Immunogenetics*, 45:379-385 (1997)) reference.

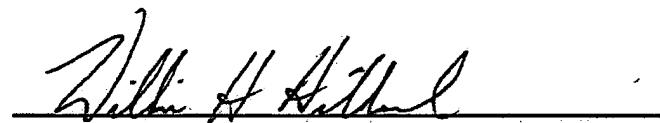
The purification procedure described in Prilliman et al. is useful for the purification of peptides from a denatured HLA trimolecular complex. The purification procedure described in Prilliman et al. is not useful for the

isolation of functionally intact HLA trimolecular complexes. In the purification procedure described in Prilliman et al., soluble HLA trimolecular complexes were produced in a lymphoblastoid cell line in culture, and the supernatants were subjected to affinity chromatography, wherein HLA light chain-specific antibodies (BBM.1) were coupled to the affinity column. The column elution procedure utilized in the method was acetic acid, pH 2.0. Under these conditions, the HLA trimolecular complexes were denatured. Therefore, the purification procedure described in Prilliman et al. isolates peptides but not intact HLA trimolecular complexes.

Thus, no functionally active, MHC trimolecular complexes can be purified substantially away from other proteins and maintain the physical, functional and antigenic integrity of the native MHC trimolecular complex using the method of Prilliman et al. In contrast, the methods described and claimed in the subject application utilize recombinantly produced, functionally active and intact HLA trimolecular complexes that have been purified substantially away from other proteins.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



William H. Hildebrand